K041521

JUN 2 2 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

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3000 North Grandview Blvd.
Waukesha, WI 53188 USA
Date Prepared: March 10, 2004.

PRODUCT IDENTIFICATION

Name: Volume Viewer Plus

Classification Name: Accessory to Computed Tomography System
Accessory to Magnetic Resonance diagnostic device

Manufacturer : General Electric Medical Systems
283, rue de la Minière
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Buc, France.

Marketed Devices The Volume Viewer Plus is substantially equivalent to the devices listed below:

- Model: Advantage Windows Volume Rendering Option
- Manufacturer: General Electric Medical Systems, Buc, France
  510(k) #: K972399
- Model: CT Colonography / Navigator2
- Manufacturer: General Electric Medical Systems, Buc, France
  510(k) #: K012313

Device Description:

Volume Viewer Plus is a software package to be used on the GE Advantage Workstation, the GE Centricity PACS Workstation and the GE CT Operator Consoles (LightSpeed and HiSpeed). It allows

the 3D processing, review and analysis of DICOM CT, MR, X-Ray Angio and PET images previously acquired, reconstructed and transferred on the corresponding workstation.
This software provides Multi-Planar Reformation (MPR) views in any plane (orthogonal, oblique or curved), 3D views in any rendering mode (MIP, MinIP, Average, Volume Rendering, Fly-Through) and their correlation to originally acquired images. Its user interface provides the tools to manipulate, annotate, measure and record these views as well as output an exam report. Additional features allow for segmentation of anatomy as well as display of multi-phase and/or fused hybrid images (PET/CT, PET/MR).

Indications for Use:

Volume Viewer Plus is a medical diagnostic software that allows the processing, review, analysis and communication of 3D reconstructed images and their relationship to originally acquired images from CT, MR, X-Ray Angio and PET Scanning devices. The combination of acquired images, reconstructed images, annotations and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information for diagnosis, surgery and treatment planning.

Comparison with Predicate:

Volume Viewer Plus is substantially equivalent to the predicate devices listed above and provides additional processing capabilities with standard review protocols per anatomy and acquisition technique (One Touch, Layout Presets, Compare Mode), enhanced segmentation tools (AutoSelect, Multi-Object Volume Rendering), enhanced visualization tools (Fused Display, Dynamic Volume Review, ROI Tool) and finally real-time interactive exporting tools (Batch Reformat/Filming, Movie Builder).

Device Name	FDA Clearance Number
Advantage Windows Volume Rendering Option	K972399
CT Colonography / Navigator2	K012313

Adverse Effects on Health:

The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:

The Volume Viewer Plus does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Volume Viewer Plus to be equivalent to those of Advantage Windows Volume Rendering Option (K972399) and CT Colonography / Navigator2 (K012313).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

General Electric Medical Systems
% Mr. Tamas Borsai
Program Manager
TUV Rheinland of North America
1279 Quarry Lane, Suite A
PLEASANTON CA 94566

Re: K041521
Trade/Device Name: Volume Viewer Plus
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 JAK and LNH
Dated: June 7, 2004
Received: June 8, 2004

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041521

General Electric Medical Systems

STATEMENT OF INDICATION FOR USE

Device name: Volume Viewer Plus

Indication for Use:

Volume Viewer Plus is a medical diagnostic software that allows the processing, review, analysis and communication of 3D reconstructed images and their relationship to originally acquired images from CT, MR, X-Ray Angio and PET Scanning devices. The combination of acquired images, reconstructed image annotations and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information for diagnosis, surgery and treatment planning.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____ (Per 21 CFR 801.109)

Jerome Zurkowski 16 Apr 2004

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K041521